US ERA ARCHIVE DOCUMENT





Meeting Minutes

Less than Lifetime Committee

April 4, 1994

Attendees:

Karl Baetcke
Bill Burnam
Larry Dorsey
Beth Doyle
Reto Engler
Karen Hamernick

Pam Hurley Mike Ioannou Sue Makris Myron Ottley Jim Rowe Clark Swentzel

Marcia van Gemert

The endpoints selected for use in less than lifetime occupational/residential and dietary risk assessments for chemicals considered at the April 4, 1994 Less than Lifetime Committee meeting are summarized below.

Pyridaben 12 9105

No dermal absorption study was available. Based upon a comparison of the Maternal NOEL in rats from a developmental toxicity study (426801-39) and the NOEL from a 21-dermal toxicity study in rats (426801-30), dermal absorption is approximately 10%.

No endpoint appropriate for use in an acute dietary risk assessment was identified.

A short term occupational exposure assessment was not required. The 21-day dermal NOEL = 100 mg/kg/day; LOEL = 300 mg/kg/day. The intermediate term occupational exposure assessment is required. Although the 21-day dermal absorption study has a relatively high NOEL, the results of a 90-day oral toxicity study in dogs (426801-27) suggest the possibility that there may be substantial interspecies variation in sensitivity. For this exposure assessment, the endpoint for consideration is the NOEL = 1.4 mg/kg/day and the LOEL = 4.0 mg/kg/day based upon clinical signs of toxicity and decreased body weight gain.

MON 12000 12872

No dermal absorption data are available; therefore, assume 100%. An acute DRES run is required based upon a rabbit developmental toxicity study (421394-26). The effect of concern was increased resorptions and postimplantation loss at 150 mg/kg/day with an NOEL = 50 mg/kg/day. An uncertainty factor of 100 should be applied.

No short or intermediate term occupational exposure assessments

are required because the 21-day dermal study had an NOEL = 100 mg/kg/day, with an LOEL = 1000 mg/kg/day.

Pyrithiobac Sodium D18 95

No dermal absorption data are available.

An acute DRES run is not required as no appropriate endpoint was identified. The developmental LOEL was approximately 1000 mg/kg/day.

No short or intermediate term exposure assessments are required as the 21-day dermal NOEL = 500 mg/kg/day and no other appropriate endpoint was identified.

Imidocloprid (W

An acute DRES run is required. In a developmental toxicity study in rabbits (422563-38), an NOEL for maternal and developmental effects of 24 mg/kg/day was reported, with an LOEL of 72 mg/kg/day based upon decreased body weights, and increased resorptions, abortion, and increased skeletal abnormalities. An uncertainty factor of 100 should be used. No short or intermediate term occupational exposure assessments are required because the NOEL for the 28-day inhalation study is the highest dose tested, and the NOEL for the 21-day dermal toxicity study is 1000 mg/kg/day.

Ethalfluralin 113101

Dermal absorption is 2.8%. An acute DRES run is required based upon the results of a developmental toxicity study in rabbits (250956). The maternal and fetotoxic NOELs were 75 mg/kg/day and the LOELs were 150 mg/kg/day based upon increased resorptions and abortions. An uncertainty factor of 100 should be applied. The same endpoint should be used for short and intermediate term occupational exposure assessments. An NOEL of 12.5 mg/kg/day from a 3-generation reproduction study in rats was also considered. However, this endpoint of reduced body weights in males was not used because of the questionable relevance for use in risk assessment.

2-Mercaptobenzothiazole

No dermal absorption data are available; assume 100%. No acute DRES run is required at this time because no food uses are currently under consideration. If food uses are proposed, the database will be reconsidered at that time. Short and intermediate term occupational exposure assessments are required. The endpoint for consideration is increased liver

weights with an NOEL of 200 mg/kg/day and and LOEL of 1000 mg/kg/day from a 13-week dermal toxicity study in rats (421463-01). Although this study has effect levels in excess of the 100 mg/kg/day cutoff normally used for occupational exposure assessments, the exposure from uses for 2-mercaptobenzothiazole (metal cutting fluid preservative) is anticipated to be high, possibly in excess of the 1 mg/kg/day exposure limit for use of the 100 mg/kg/day default.

Imazethapyr

128922

No dermal absorption data are available; assume 100%. No acute DRES run is required as no appropriate endpoints were identified.

No short or intermediate term occupational exposure are required. The NOEL from the 21-day dermal toxicity study is > 1000 mg/kg/day. The LOEL from the the multigeneration reproduction study in rats is \approx 1175 mg/kg/day.

Paclobutrazol 12563

Dermal absorption is 24.5% (24 hours). No acute DRES run is required. No endpoints appropriate for this assessment were identified. The results of four developmental toxicity studies in rats indicated no acute endpoint. No short term occupational exposure assessment is required. Although one developmental toxicity study in rats reported renal dilatation at 40 mg/kg/day, the effect was not reproduced in three other developmental studies. The NOEL for systemic effects from a 21-day dermal toxicity study was 1000 mg/kg/day on intact skin.

An intermediate term occupational exposure assessment is required. The endpoint for this assessment is an NOEL of 2.5 mg/kg/day from a 2-generation reproduction study in rats (407343-03), with an LOEL of 12.5 mg/kg/day based upon systemic effects. This study is also the basis for the RfD.

Fenbuconazole '

Dermal absorption is 12.35%.

No acute DRES run is required as no appropriate acute endpoint was identified.

A short term occupational exposure assessment is required. The endpoint of concern is the developmental NOEL of 30 mg/kg/day from a developmental toxicity study in rabbits (418750-14, 428827-01) with an LOEL of 60 mg/kg/day based upon increased resorptions (total litter death). This effect occurred at a dose in excess of the maternally toxic level (NOEL = 10 mg/kg/day, LOEL = 30 mg/kg/day based upon decreased body weights), and may

be due to maternal stress. An intermediate term occupational exposure assessment is required. The endpoint for this assessment is the NOEL of 1.3 mg/kg/day from a 90-day oral toxicity study in rats (410735-02), with an LOEL of 5.1 mg/kg/day based upon abnormal liver histopathology. This endpoint is supported by similar observations in the 90-day mouse (NOEL = 3.8 mg/kg/day, LOEL = 11.1 mg/kg/day), 90-day dog (NOEL = 3.3 mg/kg/day, LOEL = 13.3 mg/kg/day) and multigeneration reproduction study in rats (NOEL = 4 mg/kg/day, LOEL = 40 mg/kg/day).

MINUTES OF THE TESC MEETING OF 2-20-96

Attendees:

William Burnam Clark Swentzel

Mike loannou Jim Row Marion Copley Karen Hamernik

Ed Budd Alberto Protezel Stephen Dapson Jess Rowland Kathy Boyle

Chemicals Reviewed: Alachlor;

Imazalil

FINAL DOCUMENT DUE DATE: 3/05/96

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ALACHLOR - Presented by S. Dapson

REVISIT

<u>Dermal absorption:</u> 24% based on studies in Monkeys. No change from determination made on 3/21/94.

<u>Acute Dietary:</u> No appropriate end-point/study is available to use in this risk assessment. This risk assessment is not required. No change from previous determination.

<u>Short-term - Dermal Exposure:</u> Dose: 150 mg/kg/day, this NOEL for maternal and fetotoxicity was established in a developmental toxicity study in rats (MRID # 00243506 & 00043645). The NOEL is based on hairloss, soft stools, anogenital staining, increased mortality, increased post-implantation loss and a reduced number of liver fetuses.

This dose/endpoint is a new input and rescinds the previous decision.

Intermediate- Dermal: Dose: 5 mg/kg/day, this LOEL is based on increased relative and absolute liver weights in male dogs in a 6-month dog study (MRID # 246292, 246293 and 247376).

An uncertainty factor of 100 and a modifying factor of 3 (for a total of 300) should be used in MOE calculations due to the lack of a NOEL in the study selected.

Chronic- Dermal Exposure: Dose: NOEL of 0.01 mg/kg/day based on the 1-year dog study (MRID # 255953). The LOEL is based on hemosiderin storage in kidney and spleen. This study was also used for the RfD.

INHALATION EXPOSURE (ANY TIME PERIOD): Not a concern based on a LC50 of 1.04 mg/L, Tox. Cat. III. This risk assessment is not required.

<u>Cancer Classification:</u> The current classification is B2 with a Q₁* of 8.0E-2; however, <u>may</u> change due to the recent CPRC meeting and the change will be reflected in the Final document which is due in 2-3 weeks?.

Risk calculation for Drinking Water: Risk assessment should follow the same as food-use (i.e, the RfD and/or the MOE approach or use the Q_1 * if that holds).

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IMAZALIL - presented by Ed Budd

<u>Dermal absorption:</u> Summary adequate as described in the "draft" document presented to the TESC. Add the following line.

% absorbed: 41% at 10 hours (see summary above).

Acute Dietary: Dose: 5 mg/kg/day; NOEL based on increased resorptions and decreased live fetuses in a developmental toxicity study in rabbits MRID # 42593601).

<u>Short-term - Dermal Exposure:</u> Dose: 5 mg/kg/day, NOEL based increased resorption and decreased fetuses in a developmental toxicity study in rabbits MRID # 42593601).

<u>Intermediate- Dermal:</u> Dose: 5 mg/kg/day, the maternal & developmental NOEL based on decreased body weight gain and food consumption, increased resorptions and decreased live fetuses in a developmental toxicity study in rabbits MRID # 42593601).

<u>Chronic- Dermal Exposure:</u> Dose selected: NOEL of 2.5 mg/kg/day based on the 1-year dog study (MRID # 41328802). The LOEL is based on decreased body weights, increased AP values in males and increased liver weights and AP values in females. This study was also used for the RfD.

INHALATION EXPOSURE (ANY TIME PERIOD): Not a concern based on a LC50 of > 16 mg/L, Tox. Cat. IV. This risk assessment is not required.

MINUTES OF THE TESC MEETING OF APRIL 30,1996

Attendees: William Burnam

Jim Row Susan Makris Karl Baetcke Marion Copley Clark Swentzel Larry Dorsey Tom Campbell

Kathy Martin Jess Rowland

Chemicals Reviewed: Thiobencarb & Sulfentrazone,

FINAL DOCUMENT DUE DATE: 5/11/96

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Sulfentrazone - Presented by S. Makris

Dermal absorption: Approximately 10% (calculated value).

No dermal absorption studies are available. However, based on the maternal NOEL of 25 mg/kg/day following oral administration and a maternal NOEL of 250 mg/kg/day after dermal administration in rats, a dermal absorption rate of 10% is calculated.

Acute Dietary

Summary: Include the Executive Summary

Endpoint and Dose: 10 mg/kg/day; NOEL for developmental toxicity based on effects observed in the fetuses of dams dosed orally with sulfentrazone.

<u>Comments about dose/study:</u> The fetal effects observed were considered to be result of acute exposure.

This risk assessment is required

Short-term

Summary: Include the Executive Summary

<u>Endpoint and Dose:</u> 100 mg/kg/day; NOEL for developmental toxicity based on increased fetal alterations observed in the fetuses of dams following dermal application of sufentrazone.

Comments about dose/study: None

This risk assessment is required.

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Intermediate
Summary: See Short-term
<u>Endpoint and Dose:</u> 100 mg/kg/day; NOEL for developmental toxicity based on increased fetal alterations observed in the fetuses of dams following dermal application of sufentrazone.
Comments about dose/study: None
This risk assessment is required.

Chronic

Summary: See Short-term

<u>Endpoint and Dose:</u> 100 mg/kg/day; NOEL for developmental toxicity based on increased fetal alterations observed in the fetuses of dams following dermal application of sufentrazone.

Comments about dose/study: This NOEL is supported by the NOEL of 14 mg/kg/day established in a 2-generation reproduction study when the 10% dermal absorption rate is used; i.e., the comparable dermal dose is approximately 140 mg/kg/day (oral NOEL of 14 mg/kg/day ÷ 0.1% dermal absorption = 140 mg/kg/day). It is noted that while the reproduction study/NOEL was used to establish the RfD, the dermal developmental study/NOEL is used for this risk assessment. For the RfD, the reproduction study was selected since the route of exposure was dietary which is appropriate for Rfd. For this risk assessment, the dermal developmental toxicity is used since the route of exposure (dermal) is appropriate. In addition, although an UC factor of 300 (100 for inter-intra species variation & a Modifying Factor 3 for the nature and severity of effects observed) was used for calculating the RfD, for chronic dermal occupational/residential exposure risk assessment, an MOE of 100 should be adequate since the dose selected was from a dermal (developmental) study.

Summary: None

Endpoint and Dose: Not applicable; exposure via this route is not a concern. With the LC50 of >4.13 mg/L, sufentrazone is placed in Tox.Cat.III.

Comments about dose/study: None

This risk assessment is NOT required.

Thiobencarb - Presented by S. Dapson

<u>Dermal absorption:</u> 60.2% in 10 hours established in a dermal absorption study in rats. Include the Executive Summary.

Acute Dietary

Summary: Include the Executive Summary

<u>Endpoint and Dose:</u> 25 mg/kg/day; NOEL for developmental toxicity based on increases in reduced ossification and runts in the fetuses of dams given oral administration of thiobencarb.

<u>Comments about dose/study:</u> The fetal effects observed were considered to be result of acute exposure.

This risk assessment is required

Short-term

Summary: See Acute Dietary

<u>Endpoint and Dose:</u> 25 mg/kg/day; NOEL for developmental toxicity based on increases in reduced ossification and runts in the fetuses of dams given oral administration of thiobencarb.

Comments about dose/study: This NOEL is supported by the NOEL of 40 mg/kg/day established in a 21-day dermal toxicity study when the 60% dermal absorption rate is used; i.e., the comparable dermal dose is approximately 42 mg/kg/day (oral NOEL of 25 mg/kg/day + 0.6% dermal absorption = 42 mg/kg/day).

Summary: Include the Executive Summary of both studies.

<u>Endpoint and Dose:</u> 2 mg/kg/day; NOEL established for systemic toxicity in a subchronic neurotoxicity study as well as for parental/systemic toxicity in the 2-generation reproduction study.

<u>Comments about dose/study:</u> In addition to the NOELs being the same, the systemic toxicity seen were also similar in these two studies.

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Summary: Include the Executive Summary

Endpoint and Dose: 1 mg/kg/day; NOEL based on decreased body weight gains, food consumption, food efficiency and increased BUN levels in rats.

Comments about dose/study: This study was used to establish the RfD.

This risk assessment is required.

INHALATION EXPOSURE (ANY TIME PERIOD):

Summary:

Endpoint and Dose: Not applicable; exposure via this route is not a concern. With the LC50 of >42.8 mg/L/1-hr, thiobencarb is placed in Tox.Cat.IV.

Comments about dose/study: None

This risk assessment is NOT required.

MINUTES OF THE TESC MEETING OF APRIL 16,1996

Attendees: William Burnam

Karl Baetcke

Clark Swentzel

Jim Row

Marion Copley

William

Larry Dorsey

Steve Dapson

Dykstra Barbara Madden

Jess Rowland

Chemicals Reviewed:

Flutolanil

Esvenvalerate

Bifenthrin

FINAL DOCUMENT DUE DATE:

4/30/96

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Flutolanil - Presented by S. Dapson

<u>Dermal absorption:</u> No dermal absorption studies are available. Dermal absorption is not a concern since neither dermal nor systemic toxicity was observed following repeated dermal exposure at 1000 mg/kg/day (Limit-Dose).

Acute Dietary

Summary: None

Endpoint and Dose: Not applicable

Comments about dose/study: No appropriate endpoint was identified. No dermal or systemic toxicity was observed in rats following 15 repeated dermal application at 1000 mg/kg/day (Limit-Dose) in a 21 dermal toxicity. Also, no maternal toxicity was observed in rats following oral administration at 1000 mg/kg/day during gestation days 6-15 in a developmental toxicity study.

This risk assessment is NOT required

Short-term

Summary: None

Endpoint and Dose: Not applicable

<u>Comments about dose/study:</u> No appropriate endpoint was identified. No dermal or systemic toxicity was observed in rats following 15

repeated dermal application at 1000 mg/kg/day (Limit-Dose) in a 21 dermal toxicity. Also, no maternal toxicity was observed in rats following oral administration at 1000 mg/kg/day during gestation days 6-15 in a developmental toxicity study.

This risk assessment is NOT required.

Intermediate

Summary: None

Endpoint and Dose: Not applicable

Comments about dose/study: No appropriate endpoint was identified. No dermal or systemic toxicity was observed in rats following 15 repeated dermal application at 1000 mg/kg/day (Limit-Dose) in a 21 dermal toxicity. Also, no maternal toxicity was observed in rats following oral administration at 1000 mg/kg/day during gestation days 6-15 in a developmental toxicity study.

This risk assessment is NOT required.

Chronic

Summary: None

Endpoint and Dose:

Comments about dose/study: No appropriate endpoint was identified. No dermal or systemic toxicity was observed in rats following 15 repeated dermal application at 1000 mg/kg/day (Limit-Dose) in a 21 dermal toxicity. Also, no maternal toxicity was observed in rats following oral administration at 1000 mg/kg/day during gestation days 6-15 in a developmental toxicity study.

This risk assessment is NOT required.

INHALATION EXPOSURE (ANY TIME PERIOD):

<u>Summary:</u> None

Endpoint and Dose: Not applicable

Comments about dose/study: Exposure via inhalation is not a concern. LC50=>5.98 mg/L; Tox. Cat.III

Triflusulfuron-methyl

Dermal Absorption - Not available.

Acute Dietary - Not required. Developmental toxicity in rabbits only occurs in the presence of gastrointestinal problems in the dam. The abortions at the effect level for both maternal and developmental effects (270 mg/kg/day) occurred only in severely impaired animals after multiple dosing.

Short, Intermediate and Chronic term occupational - Not required. Based on the 21-day dermal toxicity study in rabbits, no systemic effects occurred up to the limit dose at 1000 mg/kg/day, suggesting that little absorption occurred. In addition, the molecule is large (molecular weight -) and unlikely to pass through skin. No inhalation data is available, but the LC50 suggests low inhalation toxicity (>5.1 mg/l).

Naled

This chemical is being revisited at the request of the registrant, Valent. They disagree with the endpoints previously selected for the occupational exposures, and the dermal absorption assumption.

Because of concerns about the integrity of the skin in test animals in the 28-day dermal study, the 7-day measurement of AChe from a one year dog study (oral) was discussed as an alternative. The NOEL was 0.2 mg/kg/day and the LOEL was 2 mg/kg/day based upon plasma and RBC cholinesterase inhibition.

Arguments that individuals will self-limit their exposure because of irritation were not accepted because of errors in assumptions about surface area exposed, and the possibility of repeated dermal exposures to low levels which could result in cumulative effects.

Arguments concerning dermal absorption were not accepted. The difference in physical properties is taken as evidence that DDVP is not an acceptable surrogate for Naled dermal absorption. In addition, the bromine atoms would markedly affect the dermal absorption.

After evaluation of all of the issues raised, the decision was made that the 28-day dermal study would remain the basis for the risk assessments. Further, the NOEL from the dog study supports the NOEL from the 28-day study.

During the reevaluation of the database for Naled, it was noted that inhalation data are available which are appropriate for occupational risk assessment. The cholinesterase NOEL (0.23 g/L) from the 90-day inhalation study is the basis for the short term, intermediate and chronic occupational risk assessments. At the next highest dose level, 1.29 g/L, clinical signs of cholinesterase inhibition were reported as well as cholinesterase inhibition per se. Clinical signs were reported in the 90-day study as early as day 15 after treatment. In a 21-day inhalation study, clinical signs were reported by day 5 of treatment at a treatment level of 3.4 g/L.

MINUTES OF THE LTLC MEETING OF 1-23-96

Attendees:

William Burnam Jim Rowe Paula Deschamp John Redden Bill Sette Karl Baetcke Mike Ioannou Debbie McCall Paul Chin Susan Makris Campbell

Jess Rowland Clark Swentzel Jane Smith Yung Yang Tom

Roger Gardner

Chemicals Reviewed: Dibrodicyanobutane

Phorate

Aldicarb

FINAL DOCUMENT DUE DATE: 2/06/96

DIBROMODICYANOBUTANE

Broad spectrum microbicide - non food use

<u>Dermal absorption:</u> No studies available. Based on the results of the dermal studies, dermal absorption of any consequence is not expected. In the 21-day dermal toxicity study, the NOEL for dermal toxicity less than 1000 mg/kg/day.

Acute Dietary: Non food use; risk assessment not required.

Short-term: No appropriate endpoint of concern was identified. The test material is not absorbed via the dermal route as demonstrated by a 21-day dermal toxicity study in which no systemic toxicity was observed following repeated dermal application of the test material at 0, 1000, 2000 or 4000 mg/kg/day. For systemic toxicity, the NOEL was > 4000 mg/kg/day (HDT).

The lack of systemic toxicity is corroborated by the developmental toxicity studies in rats and rabbits which indicated that the test material is not a developmental toxicant. The NOEL for developmental toxicity was >175 mg/kg/day in rats (MRID # 249004) and 60 mg/kg/day in rabbits (MRID #4340502).

Intermediate: Not required. - use same rationale as above.

Chronic: Not required. use same rationale as above.

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PHORATE

Food use chemical

<u>Dermal absorption:</u> No studies available. Dermal absorption should be 100% based on the acute oral LD50 of 2.71 mg/kg/day and dermal LD50 of 3 mg/kg/day in rats (ACCN # 114194).

Acute Dietary: Dose & endpoint selected: NOEL of 0.05 mg/kg/day; decreases in RBC and brain ChE activity and tremors were seen in both sexes of dogs at 0.25 mg/kg/day in a 1-year feeding study in dogs (MRID #4017452).

This dose was selected for acute dietary risk assessment because this dose/endpoint was used to establish the RfD and the ChE NOEL of this study (mentioned above) was comparable ChE NOELs observed in 90-day studies with rats and dogs (discussed below) in which ChE activity was measured after 6-days (rats) or 1 week (dogs). The 90-day studies were not used either in the assessment of RfD or the LTL because the confidence in these studies were low (old studies which did not follow the protocol/current guidelines) and were Core classified as Supplementary.

In a 90-day dietary feeding study with rats (MRID # 92873), plasma, RBC and brain cholinesterase inhibition (ChEI) measurements were made on Day 6. At 0.3 mg/kg/day males exhibited decreases in plasma, RBC and brain ChE while females at this dose had decreases in plasma and RBC ChE. The NOEL for ChEI was 0.1 mg/kg/day for both sexes. This 1955 study was classified as supplementary since the protocol did not adhere to the current guidelines.

In a 105-day dietary feeding study with dogs (MRID #92873), ChEI was determined at Week 1. Plasma ChE was decreased by approximately 50% at 0.05 mg/kg/day. The NOEL for ChEI was 0.01 mg/kg/day. This 1955 study was classified as supplementary due to non adherence to current guidelines.

Short-term: 0.05 mg/kg/day and 100% dermal absorption for risk assessment.

Intermediate: 0.05 mg/kg/day NOEL and 100% dermal absorption for risk assessment.

Chronic: 0.05 mg/kg/day NOEL and 100% dermal absorption for risk assessment.

Inhalation exposure: No appropriate acute or subchronic inhalation toxicity studies were available on the non-granular technical material. Consequently, phorate should be classified in Toxicity Category I and risk assessments for inhalation exposure should be inclusive of the inhalation (100%) and dermal (100%) exposures. The NOEL of 0.05 mg/kg/day used in the dermal risk assessments should also be used for this exposure scenario.

ALDICARB

<u>Dermal absorption</u>: No studies available. Although the oral LD50 of 1.3 mg/kg and the dermal LD50 of 5 mg/kg in rabbits indicate minimal dermal absorption, due to the low confidence in the data (i.e, purity of the test material was not known, values were for rabbits not rats, the vehicle used in both studies was propylene glycol, and data reviews were not available), a conservative estimate of 100% dermal absorption should be used for risk assessments.

Acute Dietary: Dose and endpoint: 0.001 mg/kg/day based on the NOEL of 0.01 mg/kg/day from an acute human exposure study and an uncertainty factor of 10. The LOEL of 0.025 mg/kg/day was based on sweating. This dose/study was also used to establish the RfD.

Additionally, the NOEL observed in humans in the above study is supported by the comparable NOELs observed in a 90-day study in dogs (NOEL = 0.009 mg/kg/day) and sunchronic neurotoxicity study in rats (NOEL = <0.05 mg/kg/day).

Short-term: dose/endpoint/rationale same as acute dietary

Intermediate-term: dose/endpoint/rationale same as acute dietary

Chronic: dose/endpoint/rationale same as acute dietary

Inhalation exposure: Due to lack of appropriate inhalation studies Aldicarb should be placed in Toxicity Category I. Risk assessments for inhalation exposure should be inclusive of the inhalation (100%) and dermal (100%) exposures. The dose for risk assessment should be 0.001 mg/kg/day (i.e., NOEL of 0.1 mg/kg/day from the human study and an UF of 10)